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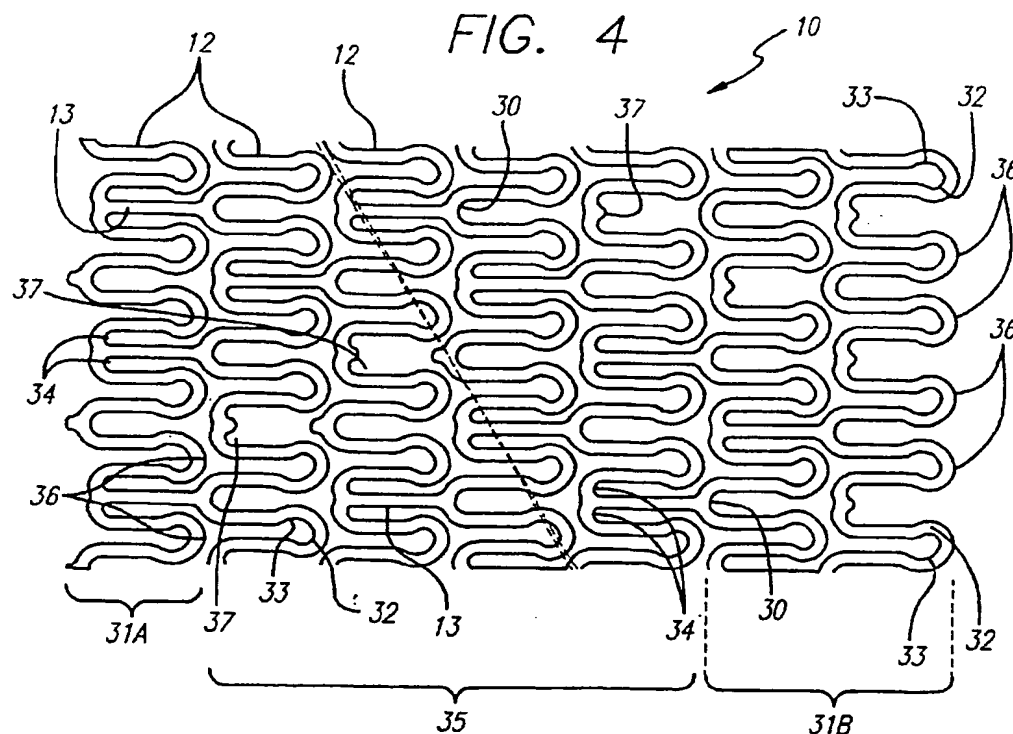
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(54) Flexible stent and method of use

(57) The invention is directed to an expandable stent for implantation in a body lumen, such as an artery. The stent consists of a plurality of radially expandable

cylindrical elements generally aligned on a common longitudinal stent axis and interconnected by one or more interconnecting members placed so that the stent is flexible in the longitudinal direction.



Description

BACKGROUND OF THE INVENTION

[0001] This invention relates to expandable endoprosthesis devices, generally known as stents, which are designed for implantation in a patient's body lumen, such as blood vessels to maintain the patency thereof. These devices particularly are useful in the treatment and repair of blood vessels after a stenosis has been compressed by percutaneous transluminal coronary angioplasty (PTCA) or percutaneous transluminal angioplasty (PTA), or has been removed by atherectomy or other means.

[0002] Stents generally are cylindrically-shaped devices which function to hold open and sometimes expand a segment of a blood vessel or other lumen such as a coronary artery. Stents particularly are suitable for use to support the lumen or hold back a dissected arterial lining which can occlude the fluid passageway there-through.

[0003] A variety of devices are known in the art for use as stents and have included coiled wires in a variety of patterns that are expanded after being placed intraluminally on a balloon catheter; helically wound coiled springs manufactured from an expandable heat sensitive metal; and self-expanding stents inserted in a compressed state and shaped in a zigzag pattern. One of the difficulties encountered using prior stents involved maintaining the radial rigidity needed to hold open a body lumen while at the same time maintaining the longitudinal flexibility of the stent to facilitate its delivery and accommodate the often tortuous path of the body lumen.

[0004] Another difficulty has been the limited range of expandability. Certain prior art stents expand only to a limited degree due to the uneven stresses created upon the stents during radial expansion. This necessitates providing stents with a variety of diameters, thus increasing the cost of manufacture. Additionally, having a stent with a wider range of expandability allows the physician to re-dilate the stent if the original vessel size was miscalculated.

[0005] Another problem with the prior art stents has been contraction of the stent along its longitudinal axis upon radial expansion of the stent. This can cause placement problems within the artery during expansion.

[0006] Various means have been described to deliver and implant stents. One method frequently described for delivering a stent to a desired intraluminal location includes mounting the expandable stent on an expandable member, such as a balloon, provided on the distal end of an intravascular catheter, advancing the catheter to the desired location within the patient's body lumen, inflating the balloon on the catheter to expand the stent into a permanent expanded condition and then deflating the balloon and removing the catheter.

[0007] What has been needed is a stent which has an

enhanced degree of flexibility so that it can be readily advanced through tortuous passageways and radially expanded over a wider range of diameters with minimal longitudinal contraction to accommodate a greater range of vessel diameters, all with minimal longitudinal contraction. The expanded stent also of course must have adequate structural strength (hoop strength) to hold open the body lumen in which it is expanded. The present invention satisfies this need.

SUMMARY OF THE INVENTION

[0008] The present invention is directed to stents of enhanced longitudinal flexibility and configuration which permit the stents to expand radially to accommodate a greater number of different diameter vessels, both large and small, than heretofore was possible. Embodiments of stents according to the invention also have greater flexibility along the longitudinal axis to facilitate delivery through tortuous body lumens, but remain highly stable when expanded radially, to maintain the patency of a body lumen such as an artery or other vessel when implanted therein. The unique patterns of embodiments of stents according to the invention permit both greater longitudinal flexibility and enhanced radial expansibility and stability compared to prior art stents.

[0009] Each of the different embodiments of stents of the present invention include a plurality of adjacent cylindrical elements which are generally expandable in the radial direction and arranged in alignment along a longitudinal stent axis. The cylindrical elements are formed in a variety of serpentine wave patterns transverse to the longitudinal axis, each of which contains a plurality of alternating peaks and valleys. At least one interconnecting member extends between adjacent cylindrical elements and connects the elements to each other. These interconnecting members insure minimal longitudinal contraction during radial expansion of the stent in the body vessel. The serpentine patterns contain varying degrees of curvature in regions of the peaks and valleys and are adapted so that radial expansion of the cylindrical elements generally is uniform around the circumferences of the cylindrical elements during expansion of the stents from the contracted condition to the expanded condition.

[0010] The resulting stent structures are a series of radially expandable cylindrical elements which are spaced longitudinally close enough so that small dissections in the wall of a body lumen may be pressed back into position against the luminal wall, but not so close as to compromise the longitudinal flexibility of the stent both when being negotiated through the body lumens in the unexpanded state and when expanded into position. The serpentine patterns allow for an even expansion around the circumference by accounting for the relative differences in stress created by the radial expansion of the cylindrical elements. Each of the individual cylindrical elements may rotate slightly relative to their adjacent

cylindrical elements without significant deformation, cumulatively providing stents which are flexible along the length and about the longitudinal axis, but which still are very stable in the radial direction in order to resist collapse after expansion.

[0011] Each of the stents of the invention readily can be delivered to the desired luminal location by mounting it on an expandable member of a delivery catheter, for example a balloon, and passing the catheter-stent assembly through the body lumen to the implantation site. A variety of means for securing the stents to the expandable member on the catheter for delivery to the desired location is available. It presently is preferred to compress the stent onto the unexpanded balloon. Other means to secure the stent to the balloon include providing ridges or collars on the inflatable member to restrain lateral movement, using bioabsorbable temporary adhesives, or a retractable sheath to cover the stent during delivery through a body lumen.

[0012] The presently preferred structures for the expandable cylindrical elements which form the stents of the present invention generally have a circumferential serpentine pattern containing a plurality of alternating peaks and valleys. The degrees of curvature along adjacent peaks and valleys are designed to compensate for the stresses created during expansion of the stent so that expansion of each of the peaks and valleys is uniform relative to one another. This novel structure permits the stents to radially expand from first smaller diameters to any number of second larger diameters because the stress is distributed more uniformly along the cylindrical elements. This uniformity in stress distribution reduces the tendency of stress fractures in one particular region and allows high expansion rates

[0013] The different stent embodiments also allow the stents to expand to various diameters from small to large in order to accommodate different-sized body lumens, without loss of radial strength and with limited contraction of longitudinal length. The open reticulated structure of the stents provides low mass, allowing for the perfusion of blood over a large portion of the arterial wall which can improve the healing and repair of a damaged arterial lining.

[0014] In one presently preferred embodiment, the ability of the stent to treat larger diameter vessels results from increasing the number of units of the repeating pattern of peaks and valleys so that the starting compressed diameter is larger than in prior art devices. When expanded, the stent of this embodiment has sufficient coverage of the luminal wall and maintains structural integrity in resisting collapse due to forces imposed by the luminal wall.

[0015] The serpentine patterns of the cylindrical elements can have different degrees of curvature of adjacent peaks and valleys to compensate for the expansive properties of the peaks and valleys. Additionally, the degree of curvature along the peaks can be set to be different in immediately adjacent areas to compensate for

the expansive properties of the valleys adjacent to the peaks. The more even radial expansion of this design results in stents which can be expanded to accommodate larger diameters with minimal out-of-plane twisting because the high stresses are not concentrated in any one particular region of the pattern but rather are distributed more evenly among the peaks and valleys, allowing the peaks and valleys to expand uniformly. Reducing the amount of out-of-plane twisting also minimizes the potential for thrombus formation. The serpentine pattern of the individual cylindrical elements can be in phase with each other in order to reduce contraction of the stents along the length of the stent upon expansion. The cylindrical elements of the stents are plastically deformed when expanded (except when the cylindrical elements are formed from nickel titanium (NiTi) alloys) so that the stents will remain in the expanded condition upon deployment and, therefore, the cylindrical elements must be sufficiently rigid when expanded to prevent the collapse thereof in use. (With stents formed from superelastic NiTi alloys, the expansion occurs when the stress of compression is removed. This allows the phase transformation from martensite back to austenite to occur, and as a result the stent expands.)

[0016] After the stents are expanded, some of the peaks and/or valleys may, but will not necessarily, tip outwardly and embed in the vessel wall. Thus, after expansion, the stents may not have a smooth outer wall surface, but rather an outer wall surface that is characterized by small projections which embed in the vessel wall and aid in retaining the stents in place in the vessel. Outward projection of the tips and twisting of the struts primarily is due to the struts having a high aspect ratio. In one preferred embodiment, the strut is about 0.089 mm (0.0035 inch) and about 0.056 mm (0.0022 inch) thick, providing an aspect ratio of 1.6. An aspect ratio of 1.0 will produce less tipping and twisting.

[0017] The elongated interconnecting members which interconnect adjacent cylindrical elements should have a transverse cross-section similar to the transverse dimensions of the undulating components of the expandable cylindrical members. The interconnecting members may be formed in a unitary structure with the expandable cylindrical elements formed from the same intermediate product, such as a tubular element, or the interconnecting members may be formed independently and mechanically secured between the expandable cylindrical elements.

[0018] Preferably, the number and location of the interconnecting members can be varied in order to develop the desired longitudinal flexibility in the stent structure both in the unexpanded as well as the expanded condition. These properties are important to minimize alteration of the natural physiology of the body lumen into which the stent is implanted and to maintain the compliance of the body lumen which is internally supported by the stent. Generally, the greater the longitudinal flexibility of the stents, the easier and the more safely

the stents can be delivered to the implantation site, particularly when the implantation site is on a curved section of a body lumen, such as a coronary artery or a peripheral blood vessel, and especially saphenous veins and larger vessels.

[0019] Accordingly, in one preferred embodiment, a maximum number of interconnecting members are provided to connect the end cylindrical elements, while a minimum number of interconnecting members connect the cylindrical elements of the center of the stent. Thus, the ends are fully supported and have more mass than the center section. The center section of the stent has less mass and is highly flexible, allowing the stent to navigate very tortuous vessels during delivery.

[0020] Other features and advantages of the present invention will become more apparent from the following detailed description of the invention, when taken in conjunction with the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0021] FIGURE 1 is an elevational view, partially in section, depicting the stent embodying features of the invention mounted on a delivery catheter and disposed within a vessel.

[0022] FIG. 2 is an elevational view, partially in section, similar to that shown in FIG. 1, wherein the stent is expanded within a vessel, pressing the detached vessel lining against the vessel wall.

[0023] FIG. 3 is an elevational view, partially in section, showing the expanded stent within the vessel after the delivery catheter has been withdrawn.

[0024] FIG. 4 is a plan view of a flattened section of one embodiment of a stent according to the invention which illustrates the serpentine pattern and the varying number of interconnecting members of the stent.

[0025] FIG. 5 is an enlarged partial view of the stent of FIG. 4 depicting the serpentine pattern along the peaks and valleys that form the cylindrical elements of the stent.

[0026] FIG. 6 is a perspective view of the stent of FIG. 4 in the expanded configuration.

[0027] FIG. 7A is a plan view of a flattened section of another embodiment of a stent according to the invention illustrating four repeating patterns for each cylindrical ring or element.

[0028] FIG. 7B is a plan view of a flattened section of another embodiment of a stent according to the invention depicting four repeating patterns, and four connecting members between the cylindrical elements, and having varying degrees of curvature in the U-shaped sections.

[0029] FIG. 8 is an enlarged partial view of the stent of FIG. 7 depicting the serpentine wave pattern along peaks and valleys that form the cylindrical elements of the stent.

[0030] FIG. 9 is a plan view of a flattened section of another embodiment of a stent according to the inven-

tion which illustrates the serpentine pattern of the stent with a decreased number of interconnecting members.

[0031] FIG. 10 is a plan view of a flattened section of another embodiment of a stent according to the invention which illustrates the serpentine pattern of the stent with a decreased number of interconnections in the center section of the stent.

[0032] FIG. 11 is a plan view of a flattened section of another embodiment of a stent according to the invention which illustrates the serpentine pattern of the stent.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0033] With respect to prior art stent designs, such as the stent manufactured under the tradename MULTILINK by Advanced Cardiovascular Systems, Inc. of Santa Clara, California, a plurality of cylindrical rings are connected by three connecting members between adjacent cylindrical rings. Each of the cylindrical rings is formed of a repeating pattern of U-, Y-, and W-shaped members, typically having three repeating patterns forming each cylindrical ring. The MULTILINK stent is a commercial embodiment of the inventions disclosed and claimed in at least U.S. Patent No. 5,569,295 (Lam) and U.S. Patent No. 5,514,154 (Lau, et al.).

[0034] In order to provide a highly flexible stent adapted for insertion in larger vessels, which has the ability to provide better coverage of the luminal wall without sacrificing radial strength or flexibility, the stent of the present invention adds at least one more repeating pattern of U-, Y-, and W-shaped members to each cylindrical ring than is to be found in the aforementioned MULTILINK commercial embodiment of a stent. Further, two connecting members spaced 180° apart between adjacent cylindrical rings, provide increased flexibility in the stents of the embodiments according to the invention in contrast to stents in the prior art, which flexibility is essential for delivering the stent through tortuous anatomy and implanting it in a curved section of vessel.

[0035] FIG. 1 illustrates a first embodiment of a stent 10 incorporating features of the invention mounted onto a delivery catheter 11. The stent generally comprises a plurality of radially expandable cylindrical elements 12 disposed generally coaxially and interconnected by interconnection members 13 disposed between adjacent cylindrical elements 12. The delivery catheter 11 has an expandable portion or a balloon 14 for expanding the stent 10 within an artery 15 or other vessel. The artery 15, as shown in FIG. 1, has a dissected lining 16 which has occluded a portion of the arterial passageway.

[0036] The delivery catheter 11 onto which the stent 10 is mounted, essentially is the same as a balloon dilatation catheter conventionally used for angioplasty procedures. The balloon 14 may be formed of suitable materials such as polyethylene, polyethylene terephthalate, polyvinyl chloride, nylon and inomers such as that manufactured under the tradename SURLYN by the

Polymer Products Division of the E. I. du Pont de Nemours Company. Other polymers also may be used. In order for the stent 10 to remain in place on the balloon 14 during delivery to the site of the damage within the artery 15, the stent 10 is compressed onto the balloon. A retractable protective delivery sleeve 20 may be provided to further insure that the stents stay in place on the expandable portion of the delivery catheter 11 and to prevent abrasion of the body lumen by the open surface of the stent 10 during delivery to the desired arterial location. Other means for securing the stent 10 onto the balloon 14 also may be used, such as providing collars or ridges on the ends of the working portion, *i.e.*, the cylindrical portion, of the balloon 14. Each radially expandable cylindrical element 12 of the stent 10 may be expanded independently, therefore the balloon 14 may be provided with an inflated shape other than cylindrical, *e.g.*, tapered, to facilitate implantation of the stent 10 in a variety of body lumen shapes.

[0037] In a preferred embodiment, delivery of the stent 10 is accomplished in the following manner. The stent 10 first is mounted onto the inflatable balloon 14 on the distal extremity of the delivery catheter 11. The stent 10 may be "crimped" down onto the balloon to insure a low profile. The catheter-stent assembly can be introduced within the patient's vasculature in a conventional Seldinger technique through a sliding catheter (not shown). A guidewire 18 is disposed through the damaged arterial section with the detached or dissected lining 16 and then the catheter-stent assembly is advanced over the guidewire 18 within the artery 15 until the stent 10 is directly under the detached lining 16. The balloon 14 of the catheter 11 is expanded, expanding the stent 10 against the inside of the artery 15, which is illustrated in FIG. 2. While not shown in the drawing, the artery 15 is preferably expanded slightly by the expansion of the stent 10 to seat or otherwise fix the stent 10 to prevent movement. In some circumstances during the treatment of stenotic portions of an artery, the artery may have to be expanded considerably in order to facilitate passage of blood or other fluid therethrough. While FIGS. 1-3 depict a vessel having a detached lining 16, the stent 10 can be used for purposes other than repairing the lining, such as supporting the vessel, reducing the likelihood of restenosis, or to assist in attaching a vascular graft (not shown) when repairing an aortic abdominal aneurysm.

[0038] The stent 10 serves to hold open an artery 15 after the catheter 11 is withdrawn, as illustrated in FIG. 3. Due to the formation of the stent 10 from an elongated tubular member, the undulating component of the cylindrical elements of the stent 10 is relatively flat in transverse cross-section, so that when the stent is expanded, the cylindrical elements are pressed into the wall of the artery 15 and as a result do not interfere with the blood flow through the artery 15. The cylindrical elements 12 of the stent 10 which are pressed into the wall of the artery 15 eventually will be covered with endothelial cell

growth, which further minimizes blood flow turbulence. The serpentine pattern of the cylindrical sections 12 provide good tacking characteristics to prevent stent movement within the artery. Further, the closely spaced cylindrical elements 12 at regular intervals provide uniform support for the wall of the artery 15, and consequently are well adapted to tack up and hold in place small flaps or dissections in the wall of the artery 15 as illustrated in FIGS. 2 and 3.

[0039] In one preferred embodiment of the stent 10, as depicted in FIGS. 4 and 5, the stresses involved during expansion from a low profile to an expanded profile are much more evenly distributed among the various peaks and valleys of the stent 10. As seen in FIG. 4, a portion of the cylindrical element 12 of the stent 10 illustrates the serpentine pattern having a plurality of peaks and valleys which aid in the even distribution of expansion forces. In this first embodiment, the interconnecting members 13 serve to connect adjacent peaks and valleys of each adjacent cylindrical element 12 as described above. The various peaks and valleys generally have U, Y and W shapes in a repeating pattern to form each cylindrical element 12. During expansion, the double-curved portions (W) 34 located in the region of the valley where the interconnecting members 13 are connected, have the most mass and accordingly are the stiffest structure during deformation, while the peak portions (U) 36 are the least stiff, and the valley portions (Y) 30 have an intermediate stiffness. In this FIG. 4 embodiment, there are three repeating patterns of peaks and valleys in each cylindrical element 12, which allows the stent to be crimped to a very small profile.

[0040] The stent can be viewed in FIG. 4 as having three sections, first and second end sections 31A, 31B and a center section 35. As is shown, the end sections have interconnecting members 13 in each W or double-curved portion 34, thereby providing maximum support in each end of the stent.

[0041] In order to improve flexibility and more uniform expansion, every second interconnecting member 13 is removed from certain cylindrical elements as shown by members 37. Thus, with interconnecting member 13 removed from member 37 in the center section 35, there is less mass, and hence less stiffness, which affords a more flexible and uniform, even expansion. Adjacent cylindrical elements 12 thus are connected by only two interconnecting elements 13, which provides for a highly flexible stent. The interconnecting members 13 are positioned 120 degrees apart on the stent. Importantly, the stent 10 of FIGS. 2-5 has an expansion ratio from the crimped to expanded configuration in the range of about 1.0 to 5.0, while maintaining structural integrity when expanded.

[0042] Because of the design, the double curved portion 34 is the stiffest structure and the peak portion 36 is the least stiff structure, which accounts for the different stresses arising during expansion. Also, the least stiff structure or peak portion 36, is positioned between

the double curved portion 34 and the valley portion 30, which are comparatively stiffer structures. To even out the stresses, the peak portion 36 has different curvatures at regions 32 and 33. Region 33 has a larger radius than region 32 and will expand more easily. Because region 32 is adjacent the stiffer area of the double curved portion 34, both region 32 and the double curved portion 34 will expand more uniformly and more evenly distribute the expansion stresses. Further, the valley portion 30 and the double curved portion 34 also have different diameters to even out the expansion forces in relation to the peak portion 36. Due to the novel structure as described, the shortcomings of the prior art, which include out-of-plane twisting of the metal, is avoided. These differing degrees of curvature along the peak portion 36 allow for the more even expansion of the cylindrical element 12 as a whole.

[0043] Referring to FIG. 6, after expansion, portions of the various elements may turn outwardly, forming small projections 38 which will embed in the vessel wall. For example, the tip 39 of the peak portion 36 tilts outwardly upon expansion a sufficient amount to embed into the vessel wall and help secure the implanted stent 10. Upon expansion, the projections 38 provide an outer wall surface on the stent that is not smooth, but instead has a plurality of projections 38 all along the outer wall surface. While the projections 38 assist in securing the stent 10 to the vessel wall, the projections are not so sharp as to cause trauma or damage to the vessel wall. Outward projection of the tips and twisting of the struts primarily is due to the struts having a high aspect ratio. In one preferred embodiment, the strut is about 0.089 mm (0.0035 inch) wide and about 0.056 mm (0.0022 inch) thick, providing an aspect ratio of 1.6. An aspect ratio of 1.0 will produce less tipping and twisting.

[0044] Referring to FIGS. 7-11, additional preferred embodiments of stents according to the invention are shown. The embodiment of the stent 40 of FIGS. 7A and 7B and 8 has the common features of four repeating serpentine wave pattern sections 43 and four interconnecting members 42 for each cylindrical element 41. All of the arcs 39a, 39b, 39c, and 39d of FIG. 8 have the same radius of curvature providing a simplified single arc pattern. In contrast, all of the arcs of FIG. 7B have different radii of curvature. The stent 40 has a plurality of cylindrical elements 41 that are connected by interconnecting members 42. Each cylindrical member 41 is made of four repeating serpentine wave pattern sections 43 with a valley portion 44, a peak portion 45, and double curve portion 46. The valley portion 44 and the peak portion 45 each have a generally single radius of curvature. The valley portion 44 is connected at both of its end areas 47 to linking portions 48 which bridge to first ends 49 of the peak portions 45. The linking portions 48 generally are straight and elongate.

[0045] As depicted in FIGS. 7A and 8, the opposite end regions 50 of the double curved portions 46 are connected to link members 51 which connect to second

ends 52 of peak portion 45. The ends of the link members 51 which are connected to the opposite ends 50 of the double curved portion, 46 lie closer in the unexpanded state to the link portions 48 than do the opposite ends of the link member, 51 which are connected to the peak portion 45 at the second end, 52 - the link members 51 are offset diagonally to the longitudinal axis of the stent. As noted above, the interconnecting members 42 connect together the adjacent cylindrical elements 41. These interconnecting members 42 preferably extend away from the valley portions 44 and the connected link portions 48 of the valley portions and extend between two link members 51 of an adjacent double curve portion 46 to join the double curve portion 46 between its two ends 49. The design of the stent 40 thus will allow a great range of expansion to enlarge the diameter thereof, such as 1.0 to 4.0 times the original diameter, or even more.

[0046] The stent 70 of FIG. 9 depicts another embodiment and is similar to the stent 40 of FIG. 7B, except that the stent 70 retains all of the interconnecting members 71 to connect cylindrical elements 73 to cylindrical element 72. In the center cylindrical elements 74, some interconnecting members are removed and preferably alternating interconnecting members are removed in the center cylindrical elements 74 which lie between the terminating cylindrical elements 72. Each of the cylindrical elements 72, 73 and 74 has four repeating serpentine wave patterns 75 which provides for maximum expansion ratio, such as for implanting in a saphenous vein.

[0047] Referring to FIG. 10, another preferred embodiment of a stent 80 according to the invention is shown, where the curvature of the peaks 81 is somewhat circular and circumscribes more than 180 degrees of curvature, for example about 240 degrees of curvature, while remaining preferably symmetrical. The radius and degree of arc can vary to provide for optimal expansion and crimping. In the unexpanded state, the linking portions 82 connecting the peaks 81 to the valleys 83 and the link member 84 connecting the peak, 81 to double curved portions 85 generally are parallel to each other. In cylindrical elements 86, which form end sections 90A, 90B, there is an interconnecting member 87 in each double curved portion 85. In the cylindrical elements 88, which are in the flexible center section 91, there is an interconnecting member 86 in every other double curved portion 85. This configuration provides a stent 80 that has less mass in the center section and which is more flexible than prior art stent structures, yet the end sections still are relatively stiff and provide substantial support. The four repeating serpentine wave patterns in each cylindrical element 86, 88 provide maximum radial expansion, structural integrity, and vessel coverage.

[0048] FIG. 11 depicts another embodiment of a stent 100 having only two interconnecting members 101 connecting adjacent cylindrical elements 102 in the center of the stent and two interconnecting members 103 are

used at terminating cylindrical elements 104. This configuration again provides a much higher degree of flexibility not found in prior art stents. The stent 100 also has fewer repeating serpentine elements 105 per each cylindrical element 111 and has a more open pattern to allow for more extensive crimping to reduce its diameter further to ensure a very low delivery profile. The stent 100 ideally is suited for placement in vessels having a diameter in the 2.0 to 3.0 mm (0.079 to 0.11 inch) range. Each cylindrical element 102 has two repeating serpentine wave patterns 105 which can be crimped to very small profiles for delivery in smaller vessels.

[0049] It should be understood that the term "interconnecting member" as used herein can include not only, those connecting elements specifically depicted in the drawings, but also welds between adjacent cylindrical elements or simply an uncut area between cylindrical elements.

[0050] The stents 10, 40, 70, 80, and 100 depicted in the drawing figures are shown with the center cut of the laser, but after subtracting the kerf width and then polishing, the valley and peak portions, link portions, link members, and interconnecting portions will have slightly narrower widths than as depicted. Further, in many of the drawing figures the stent is depicted flat, in a plan view, for ease of illustration. All of the embodiments depicted herein are cylindrically-shaped stents that are generally formed from tubing by laser cutting as will be described.

[0051] One important feature of all of the embodiments of the present invention is the capability of the stents to expand from a low-profile diameter to a diameter much greater than heretofore was available, while still maintaining structural integrity in the expanded state and remaining highly flexible. Due to the novel structures, the stents of the present invention each have an overall expansion ratio of about 1.0 up to about 4.0 times or more of the original diameter using certain compositions of stainless steel. For example, a 316L stainless steel stent of the invention can be radially expanded from a diameter of 1.0 unit up to a diameter of about 4.0 units, which deforms the structural members beyond the elastic limit. The stents still retain structural integrity in the expanded state and will serve to hold open the vessel into which the stents are implanted. Materials other than stainless steel (316L) may afford higher or lower expansion ratios without sacrificing structural integrity.

[0052] The stents of the present invention can be made in many ways. However, the preferred method of making the stent is to cut a thin-walled tubular member, such as stainless steel tubing to remove portions of the tubing in the desired pattern for the stent, leaving relatively untouched the portions of the metallic tubing which are to form the stent. It is preferred to cut the tubing in the desired pattern by means of a machine-controlled laser.

[0053] The tubing may be made of suitable biocompatible material such as stainless steel. The stainless

steel tube may be alloy-type: 316L SS, Special Chemistry per ASTM F138-92 or ASTM F139-92 grade 2. Special Chemistry of type 316L per ASTM F138-92 or ASTM F139-92 Stainless Steel for Surgical Implants in weight percent.

Carbon (C)	0.03% max.
Manganese (Mn)	2.00% max.
Phosphorous (P)	0.025% max.
Sulphur (S)	0.010% max.
Silicon (Si)	0.75% max.
Chromium (Cr)	17.00 - 19.00%
Nickel (Ni)	13.00 - 15.50%
Molybdenum (Mo)	2.00 - 3.00%
Nitrogen (N)	0.10% max.
Copper (Cu)	0.50% max.
Iron (Fe)	Balance

The stent diameter is very small, so the tubing from which it is made necessarily also must have a small diameter. Typically the stent has an outer diameter on the order of about 1.52 mm (0.06 inch) in the unexpanded condition, the same outer diameter of the tubing from which it is made, and can be expanded to an outer diameter of 5.1 mm (0.2 inch) or more. The wall thickness of the tubing is about 0.008 mm (0.0003 inch).

[0054] Generally, the tubing is put in a rotatable collet fixture of a machine-controlled apparatus for positioning the tubing relative to a laser. According to machine-encoded instructions, the tubing then is rotated and moved longitudinally relative to the laser which also is machine-controlled. The laser selectively removes the material from the tubing by ablation and a pattern is cut into the tube. The tube therefore is cut into the discrete pattern of the finished stent.

[0055] The process of cutting a pattern for the stent into the tubing generally is automated except for loading and unloading the length of tubing. For example, a pattern can be cut in tubing using a CNC-opposing collet fixture for axial rotation of the length of tubing, in conjunction with CNC X/Y table to move the length of tubing axially relative to a machine-controlled laser as described. The entire space between collets can be patterned using the CO₂ laser set-up of the foregoing example. The program for control of the apparatus is dependent on the particular configuration used and the pattern to be ablated in the coding.

[0056] Cutting a fine structure 0.086 mm ((0.0034 inch) web width) requires minimal heat input and the ability to manipulate the tube with precision. It also is necessary to support the tube yet not allow the stent structure to distort during the cutting operation. In order to successfully achieve the desired end results, the en-

tire system must be configured very carefully. The tubes are made of stainless steel with an outside diameter of 1.52 mm (0.060 inch) to 1.68 mm (0.066 inch) and a wall thickness of 0.051 mm (0.002 inch) to 0.10 mm (0.004 inch). These tubes are fixtured under a laser and positioned utilizing a CNC to generate a very intricate and precise pattern. Due to the thin wall and the small geometry of the stent pattern 0.089 mm ((0.0035 inch) typical strut width), it is necessary to have very precise control of the laser, its power level, the focused spot size, and the precise positioning of the laser cutting path.

[0057] In order to minimize the heat input into the stent structure, which prevents thermal distortion, uncontrolled burn out of the metal, and metallurgical damage due to excessive heat, and thereby produce a smooth debris-free cut, a Q-switched Nd/YAG, typically available from Quantonix of Hauppauge, New York, that is frequency-doubled to produce a green beam at 532 nanometers is utilized. Q-switching produces very short pulses (<100 nS) of high peak powers (kilowatts), low energy per pulse (≤ 3 mJ), at high pulse rates (up to 40 kHz). The frequency doubling of the beam from 1.06 microns to 0.532 microns allows the beam to be focused to a spot size that is two times smaller, therefore increasing the power density by a factor of four times. With all of these parameters, it is possible to make smooth, narrow cuts in the stainless steel tubes in very fine geometries without damaging the narrow struts that make up the stent structure. Hence, the system of the present invention makes it possible to adjust the laser parameters to cut narrow kerf width which will minimize the heat input into the material.

[0058] The positioning of the tubular structure requires the use of precision CNC equipment such as that manufactured and sold by the Anorad Corporation. In addition, a unique rotary mechanism has been provided that allows the computer program to be written as if the pattern were being cut from a flat sheet. This allows both circular and linear interpolation to be utilized in programming.

[0059] The optical system which expands the original laser beam delivers the beam through a viewing head and focuses the beam onto the surface of the tube, incorporates a coaxial gas jet and nozzle that helps to remove debris from the kerf, and cools the region where the beam interacts with the material as the beam cuts and vaporizes the metal. It also is necessary to block the beam as it cuts through the top surface of the tube and to prevent the beam, along with the molten metal and debris from the cut, from impinging on the opposite surface of the tube.

[0060] In addition to the laser and the CNC positioning equipment, the optical delivery system includes a beam expander to increase the laser beam diameter, a circular polarizer (typically in the form of a quarter wave plate) to eliminate polarization effects in metal cutting, provisions for a spatial filter, a binocular viewing head and focusing lens, and a coaxial gas jet that provides for the

introduction of a gas stream that surrounds the focused beam and is directed along the beam axis. The coaxial gas jet nozzle 0.46 mm ((0.018 inch) inner diameter) is centered around the focused beam with approximately 0.25 mm (0.010 inch) between the tip of the nozzle and the tubing. The jet is pressurized with oxygen at 1.38 bars (20 psi) and is directed at the tube with the focused laser beam exiting the tip of the nozzle 0.46 mm ((0.018 inch) diameter). The oxygen reacts with the metal to assist in the cutting process very similar to oxyacetylene cutting. The focused laser beam acts as an ignition source and controls the reaction of the oxygen with the metal. In this manner, it is possible to cut the material with a very fine kerf with precision.

[0061] In order to prevent burning by the beam and/or molten slag on the far wall of the tube inner diameter (I.D.), a stainless steel mandrel (approximately 0.86 mm (0.034 inch) diameter) is placed inside the tube and is allowed to roll on the bottom of the tube as the pattern is cut. This acts as a beam/debris barrier protecting the far wall inner diameter (I.D.)

[0062] Alternatively, this may be accomplished by inserting a second tube inside the stent tube which has an opening to trap the excess energy in the beam which is transmitted through the kerf and to collect the debris that is ejected from the laser cut kerf. A vacuum or positive pressure can be placed in this shielding tube to remove the collection of debris.

[0063] Another technique that could be utilized to remove the debris from the kerf and to cool the surrounding material would be to use the inner beam blocking tube as an internal gas jet. By sealing one end of the tube and making a small hole in the side and placing the tube directly under the focused laser beam, gas pressure could be applied creating a small jet that would force the debris out of the laser cut kerf from the inside out. This would eliminate any debris from forming or collecting on the inside of the stent structure. It would place all the debris on the outside. With the use of special protective coatings, the resultant debris can be easily removed.

[0064] In most cases, the gas utilized in the jets may be reactive or non-reactive (inert). In the case of reactive gas, oxygen or compressed air is used. Oxygen is used in this application since it offers more control of the material removed and reduces the thermal effects of the material itself. Inert gases such as argon, helium, or nitrogen can be used to eliminate any oxidation of the cut material. The result is a cut edge with no oxidation, but there usually is a tail of molten material that collects along the exit side of the gas jet that must be removed mechanically or chemically after the cutting operation.

[0065] The cutting process utilizing oxygen with the finely focused green beam results in a very narrow kerf (approximately 0.013 mm (0.0005 inch)) with the molten slag re-solidifying along the cut. This traps the cut-out scrap of the pattern requiring further processing. In order to remove the slag debris from the cut allowing the

scrap to be removed from the remaining stent pattern, it is necessary to soak the cut tube in a solution of hydrochloric acid (HCL) for approximately eight minutes at a temperature of approximately 55° C. Before it is soaked, the tube is placed in a bath of an alcohol/water solution and ultrasonically cleaned for approximately one minute, to remove the loose debris left from the cutting operation. After soaking, the tube is cleaned ultrasonically in the heated HCL for one to four minutes depending upon the wall thickness. To prevent cracking/breaking of the struts attached to the material left at the two ends of the stent pattern due to harmonic oscillations induced by the ultrasonic cleaner, a mandrel is placed down the center of the tube during the cleaning/scrap removal process. At completion of this process, the stent structures are rinsed in water. The stents then are ready for electropolishing.

[0066] The stents preferably are electrochemically polished in an acidic aqueous solution such as a solution of ELECTRO-GLO #300, sold by the ELECTRO-GLO Co., Inc. in Chicago, Illinois, which is a mixture of sulfuric acid, carboxylic acids, phosphates, corrosion inhibitors and a biodegradable surface active agent. The bath temperature is maintained at about 43°-56° C (110-133°F) and the current density is about 0.06 to 0.23 amps per cm² (about 0.4 to about 1.5 amps per in²). The cathode to anode area should be at least about two to one. The stents may be further treated if desired, for example by applying a biocompatible coating.

[0067] Direct laser cutting produces edges which are essentially perpendicular to the axis of the laser cutting beam, in contrast with chemical etching and the like which produce pattern edges which are angled. Hence, the laser cutting process of the present invention essentially provides stent cross-sections, from cut-to-cut, which are square or rectangular, rather than trapezoidal. The resulting stent structure provides superior performance.

[0068] The stent tubing may be made of suitable biocompatible material such as stainless steel, titanium, tantalum, superelastic nickel-titanium (NiTi) alloys and even high strength thermoplastic polymers. The stent diameters are very small, so the tubing from which it is made necessarily also must have a small diameter. For percutaneous transluminal coronary angioplasty (PTCA) applications, typically the stent has an outer diameter on the order of about 1.65 mm (0.065 inches) in the unexpanded condition (the same as the outer diameter of the hypotubing from which it is made) and can be expanded to an outer diameter of 5.08 mm (0.2 inches) or more. The wall thickness of the tubing is about 0.076 mm (0.003 inches). For stents implanted in other body lumens, such as percutaneous transluminal angioplasty (PTA) applications, the dimensions of the tubing correspondingly are larger. While it is preferred that the stents be made from laser cut tubing, those skilled in the art will realize that the stent can be laser cut from a flat sheet and then rolled up in a cylindrical configuration with the

longitudinal edges welded to form a cylindrical member. [0069] In the instance when the stents are made from plastic, the implanted stent may have to be heated within the arterial site where the stents are expanded to facilitate the expansion of the stent. Once expanded, the stent then would be cooled to retain its expanded state. The stent conveniently may be heated by heating the fluid within the balloon or by heating the balloon itself directly by a known method.

[0070] The stents also may be made of materials such as superelastic (sometimes called pseudo-elastic) NiTi alloys. In this case the stent would be formed full size but deformed (e.g., compressed) to a smaller diameter onto the balloon of the delivery catheter to facilitate intraluminal delivery to a desired intraluminal site. The stress induced by the deformation transforms the stent from an austenite phase to a martensite phase, and upon release of the force when the stent reaches the desired intraluminal location, the stent is allowed to expand due to the transformation back to the more stable austenite phase. Further details of how NiTi superelastic alloys operate can be found in U.S. Patent Nos. 4,665,906 (Jervis) and 5,067,957 (Jervis).

[0071] While the invention has been illustrated and described herein in terms of its use as intravascular stents, it will be apparent to those skilled in the art that the stents can be used in other instances in all vessels in the body. Because the stents of the present invention have the novel feature of being capable of expanding to very large diameters while retaining their structural integrity, the stents are particularly well suited for implantation in almost any vessel where such devices are used. This feature, coupled with limited longitudinal contraction of the stent when the devices are expanded radially, provide a highly desirable support member for all vessels in the body. Other modifications and improvements may be made without departing from the scope of the invention.

Claims

1. A longitudinally flexible stent (10) for implanting in a body lumen and expandable from a contracted condition to an expanded condition, comprising:

a plurality of adjacent cylindrical elements (12) each having a circumference extending around a longitudinal stent axis, the elements being arranged in cylindrical alignment along the longitudinal stent axis to form a generally tubular member;

the generally tubular members having a first end section (31A), a second end section (31B), and a center section (35) therebetween; and the adjacent cylindrical elements (12) in the first and the second end sections (31A, 31B) being connected by n interconnecting members (13),

- and the adjacent cylindrical elements (12) in the center section (35) being connected by $n - 1$ interconnecting members (13), whereby the center section (35) is relatively more flexible than the first and the second end sections (31A, 31B) which have more interconnecting members (13) than the center section (35). 5
2. The stent of claim 1, wherein the center section (35) includes adjacent cylindrical elements (12) connected by $n - 2$ interconnecting members (13). 10
 3. The stent of claim 1, wherein the center section (35) includes adjacent cylindrical elements (12) connected by $n - 3$ interconnecting members (13). 15
 4. The stent of claim 1, wherein the center section (35) includes adjacent cylindrical elements (12) connected by at least one interconnecting member (13). 20
 5. The stent of claim 1, wherein each cylindrical element (12) is formed in a generally serpentine wave pattern transverse to the longitudinal axis, the serpentine wave pattern having a plurality of alternating peak portions (36), valley portions (30) and double-curved portions (34). 25
 6. The stent of claim 5, wherein the n and the $n - 1$ interconnecting members (13) connect the valley (30) of one cylindrical element (12) with a double-curved portion (34) of an adjacent cylindrical element (12). 30
 7. The stent of claim 1, wherein the cylindrical elements (12) are configured for expanding from a first smaller diameter to a range of enlarged diameters without appreciable change in the length of the stent. 35
 8. The stent of claim 5, wherein the peak portions (36) have irregular radii of curvature (32, 33) so that upon expansion, the peak portions (36) uniformly and evenly expand. 40
 9. The stent of claim 1, wherein the stent is formed from a flat piece of material. 45
 10. The stent of claim 1, wherein the stent is formed of a biocompatible material selected from the group consisting of stainless steel, tungsten, tantalum, super elastic nickel-titanium alloys, and thermoplastic polymers. 50
 11. The stent of claim 1, wherein the stent has a radial expansion ratio of about 1.0 in the contracted condition up to about 4.0 in the expanded condition. 55
 12. The stent of claim 1, wherein the stent is formed from a single piece of tubing.
 13. A longitudinally flexible stent (10) for implanting in a body lumen and expandable from a contracted condition to an expanded condition, comprising:

a plurality of adjacent cylindrical elements (12) each having a circumference extending around a longitudinal stent axis and each element being substantially independently expandable in the radial direction, each element being arranged in alignment along the longitudinal stent axis;

the cylindrical elements (12) formed in a generally serpentine wave pattern transverse to the longitudinal axis and containing alternating valley portions (30), peak portions (36) and double-curved portions (34), each cylindrical element (12) being arranged so that the peaks (36) of adjacent cylindrical elements (12) are out of phase;

a plurality of interconnecting members (13) extending between the adjacent cylindrical elements (12) and connecting valley portions (30) and double-curved portions (34) of adjacent cylindrical elements (12) to one another;

the stent having a first end section (31A), a second end section (31B) and a center section (35) therebetween, the plurality of interconnecting members (13) being positioned in the first end section (31A), the second end section (31B), and the center section (35) so that the center section is longitudinally more flexible than the first and the second end sections.
 14. The stent of claim 13, wherein the shape and size along adjacent peak portions (36) and valley portions (30) of the serpentine pattern are different.
 15. The stent of claim 13, wherein the cylindrical elements (12) cooperate to define a generally smooth cylindrical surface and wherein the peak portions (36) form projecting edges (38) which project outwardly from the cylindrical surface upon expansion.
 16. The stent of claim 13, wherein said stent is formed of a biocompatible material selected from the group consisting of stainless steel, tungsten, tantalum, super elastic nickel-titanium alloys, and thermoplastic polymers.
 17. The stent of claim 13, wherein said stent has a radial expansion ratio of about 1.0 in the contracted condition up to about 4.0 or more in the expanded condition.
 18. The stent of claim 13, wherein the stent is formed

from a single piece of tubing.

19. A longitudinally flexible stent (10) for implanting a body lumen and expandable from a contracted condition to an expanded condition, comprising: 5

a plurality of adjacent cylindrical elements (12), each having a circumference extending around a longitudinal stent axis and each cylindrical element being expandable in the radial direction, the cylindrical elements being arranged in alignment along the longitudinal stent axis; the cylindrical elements formed in a generally serpentine wave pattern and containing a plurality of alternating peak portions (36), valley portions (30) and double-curved portions (34); the cylindrical elements (12) interconnected to form a first end section (31A), a second end section (31B), and a center section (35) therebetween; 10 15 20

the center section (35) being relatively more flexible than the first end section (31A) and the second end section (31B).

20. The stent of claim 19, wherein at least one interconnecting member (13) connects adjacent cylindrical elements (12). 25
21. The stent of claim 20, wherein each of the double-curved portions (34) in the first end section (31A) includes an interconnecting member (13). 30
22. The stent of claim 21, wherein each double-curved portion (34) in the second end section (31B) includes an interconnecting member (13). 35
23. The stent of claim 20, wherein every other double-curved portion (34) in the center section (35) includes an interconnecting member (13). 40
24. The stent of claim 20, wherein every second double-curved portion (34) of the center section (35) includes an interconnecting member (13). 45

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FIG. 1

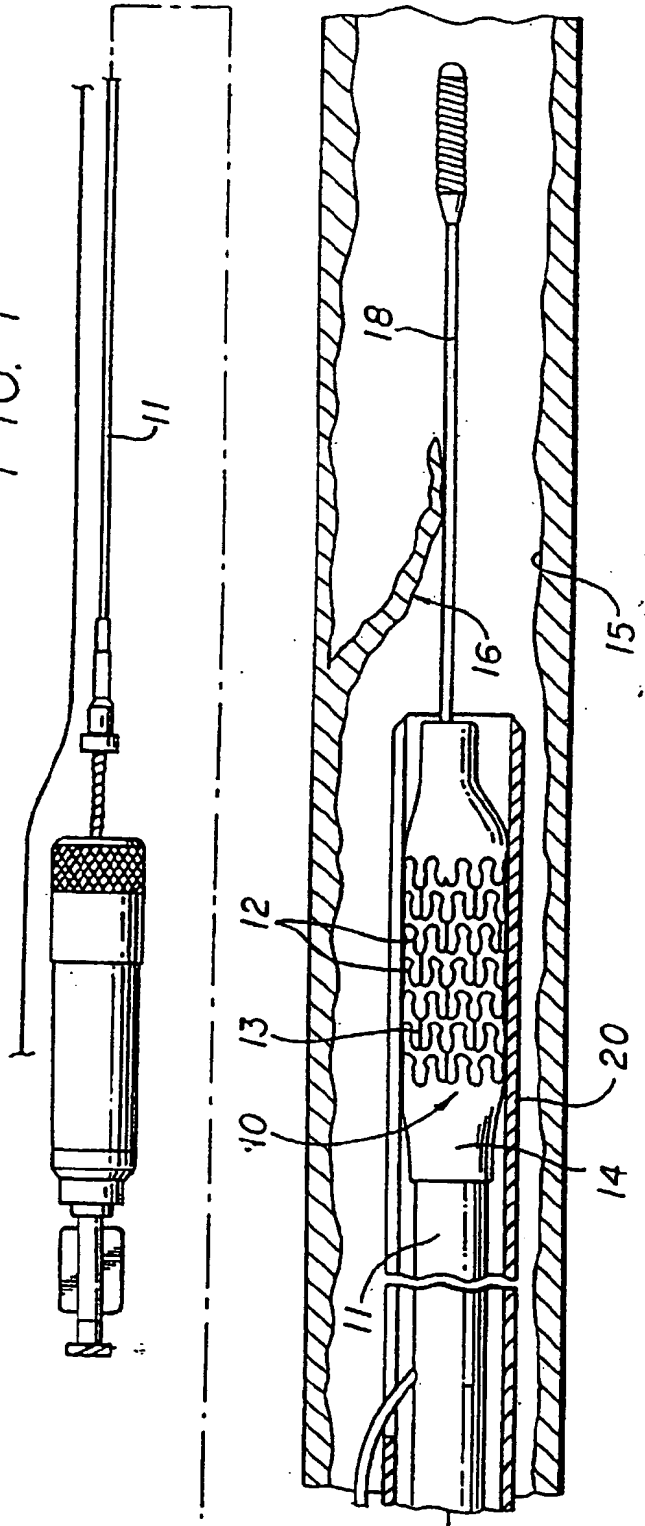


FIG. 3

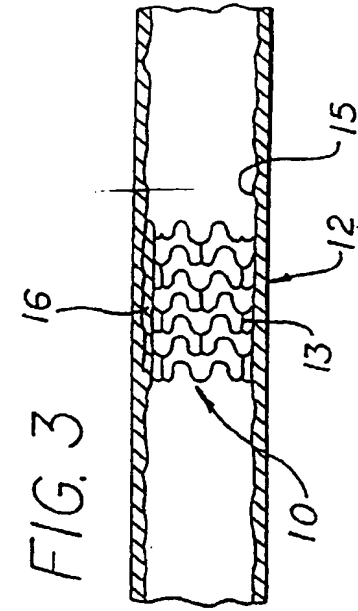


FIG. 2

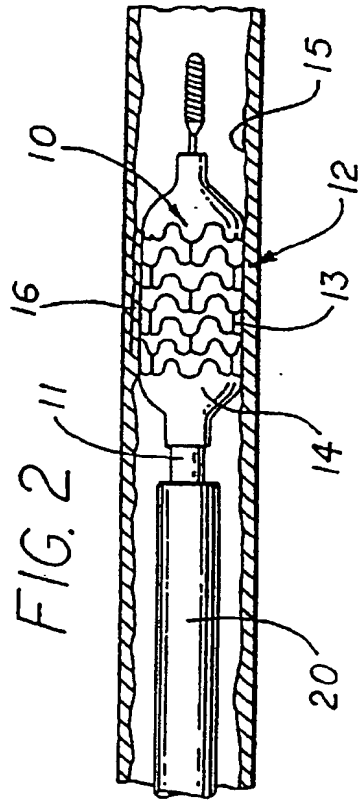


FIG. 4

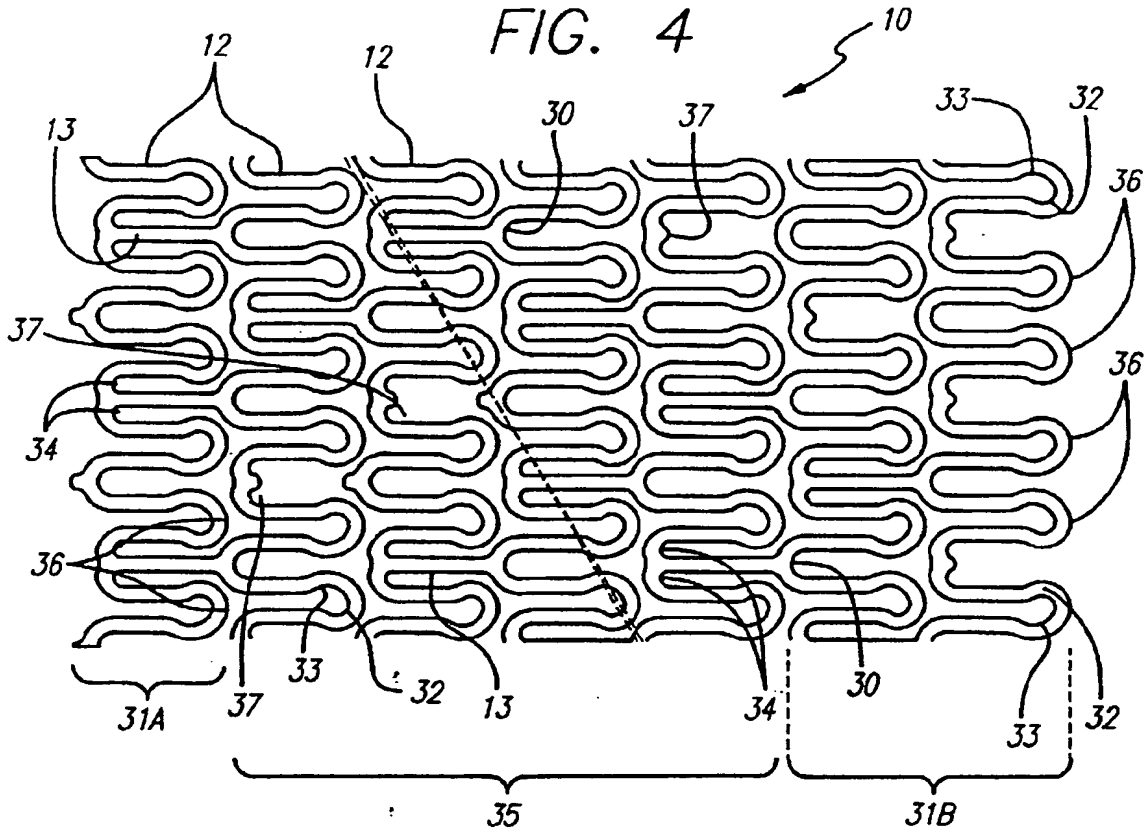
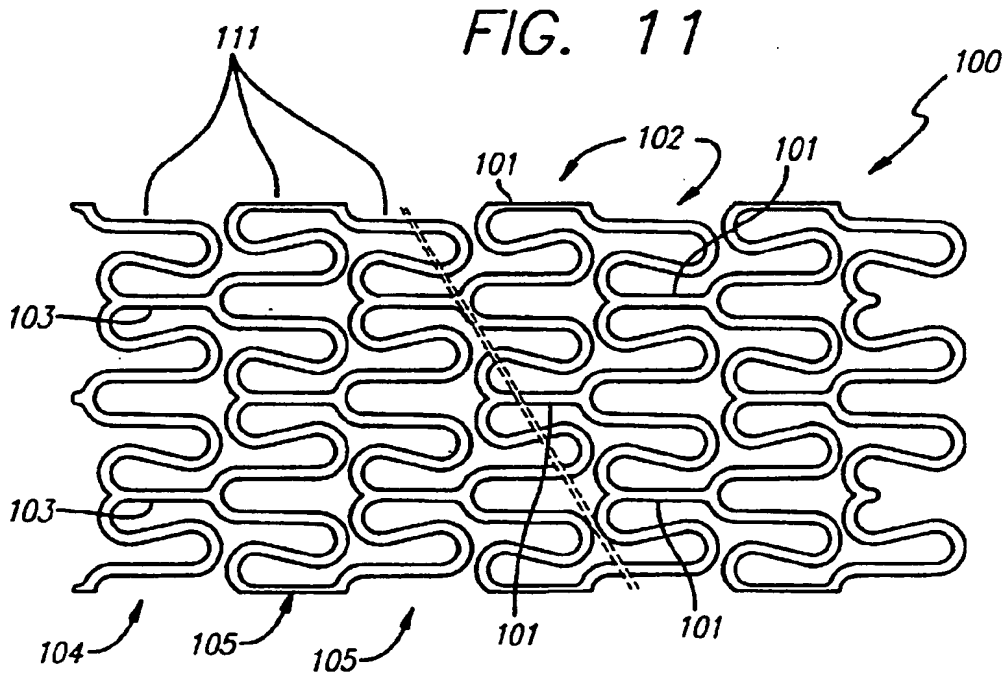


FIG. 11



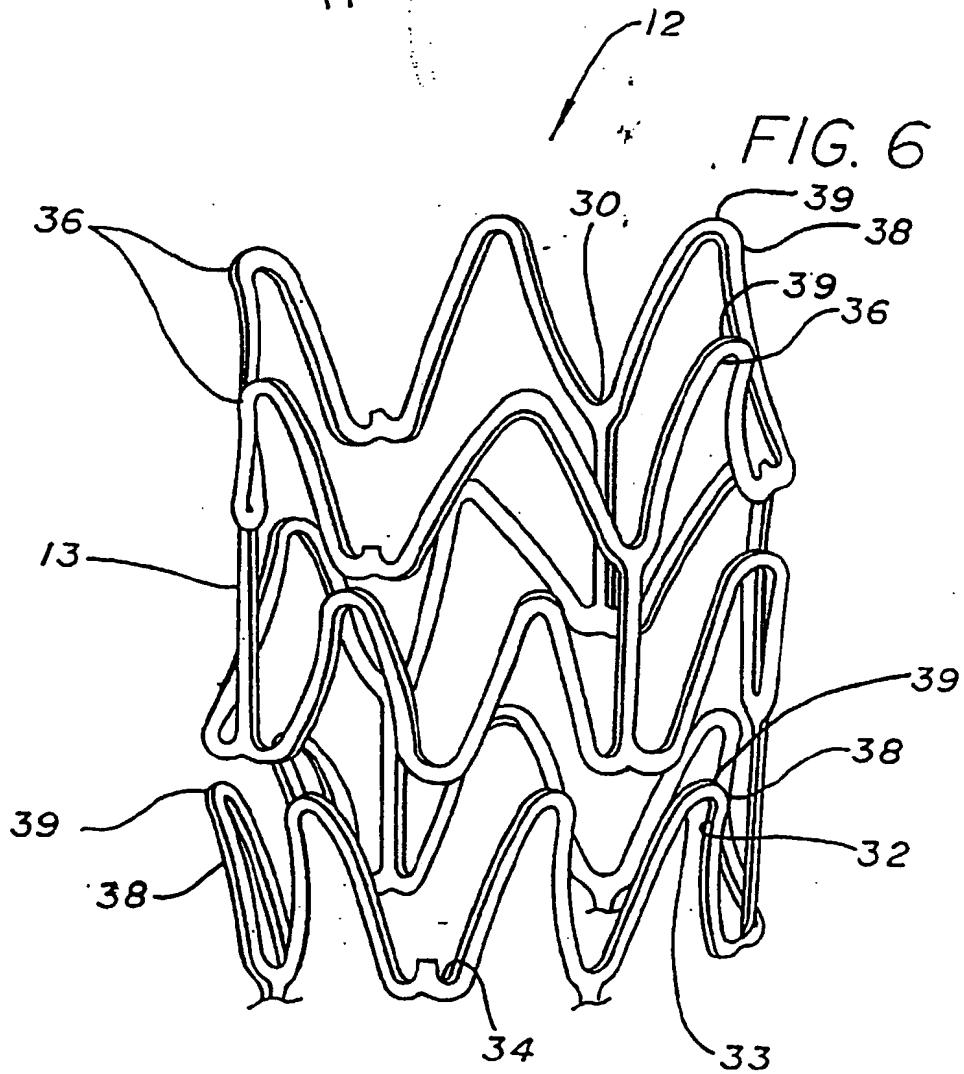
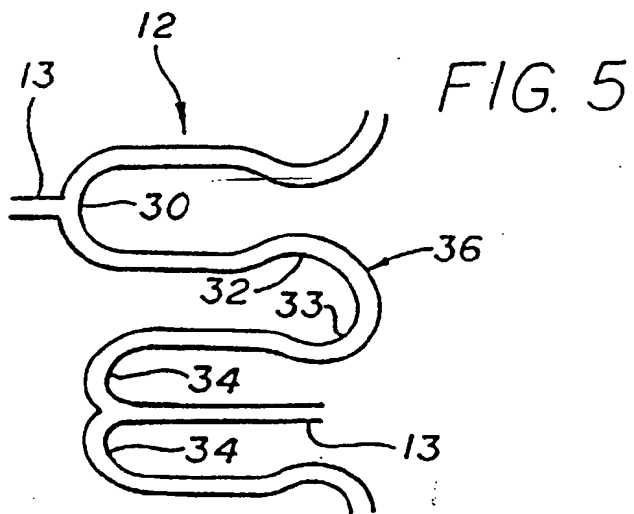


FIG. 7A

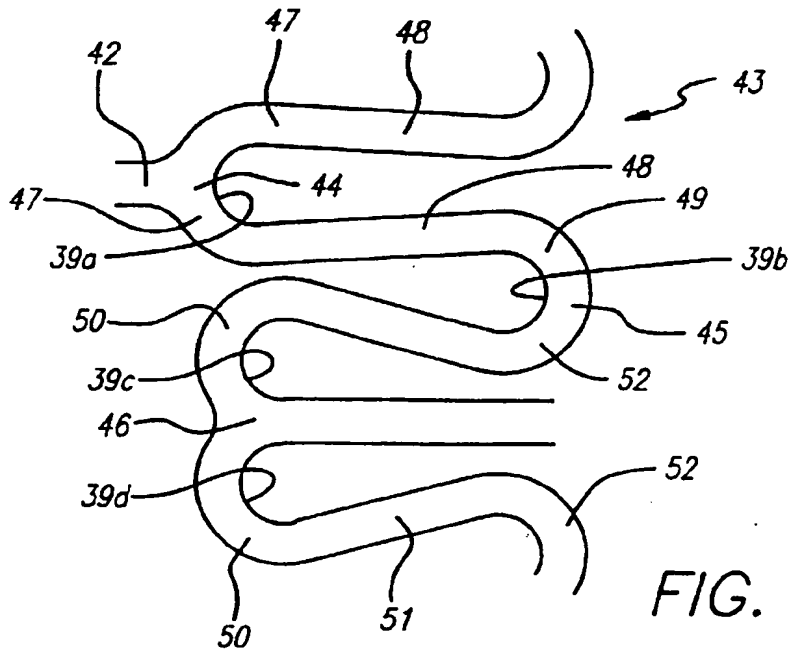
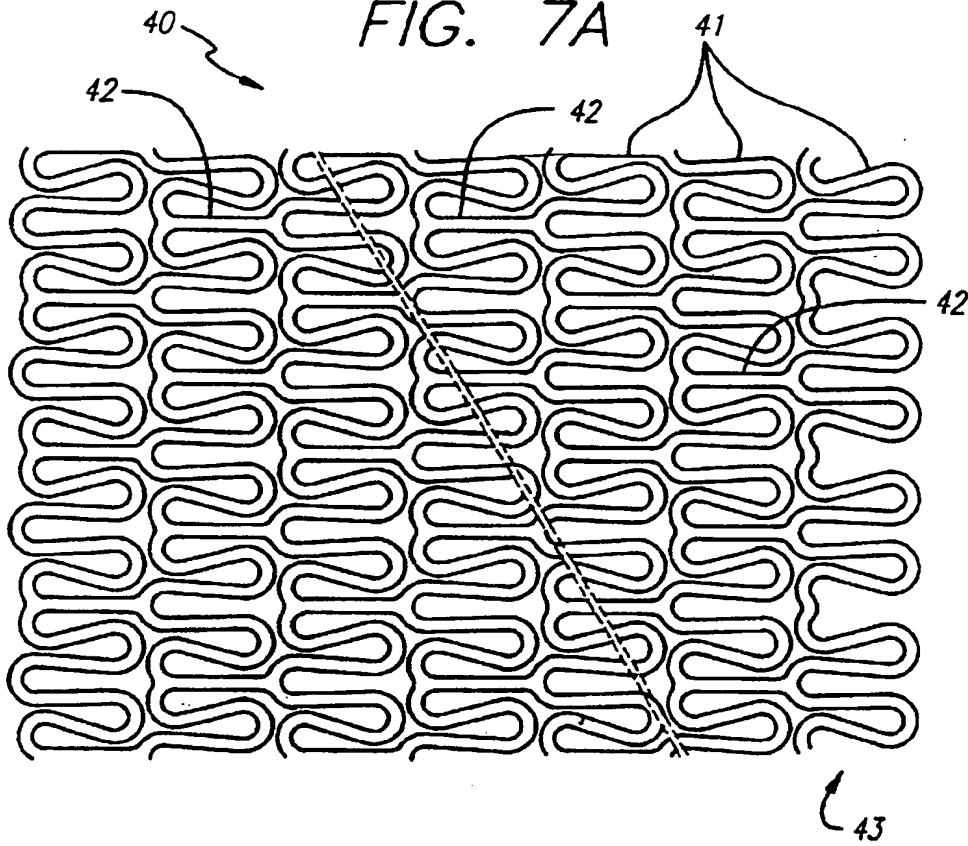
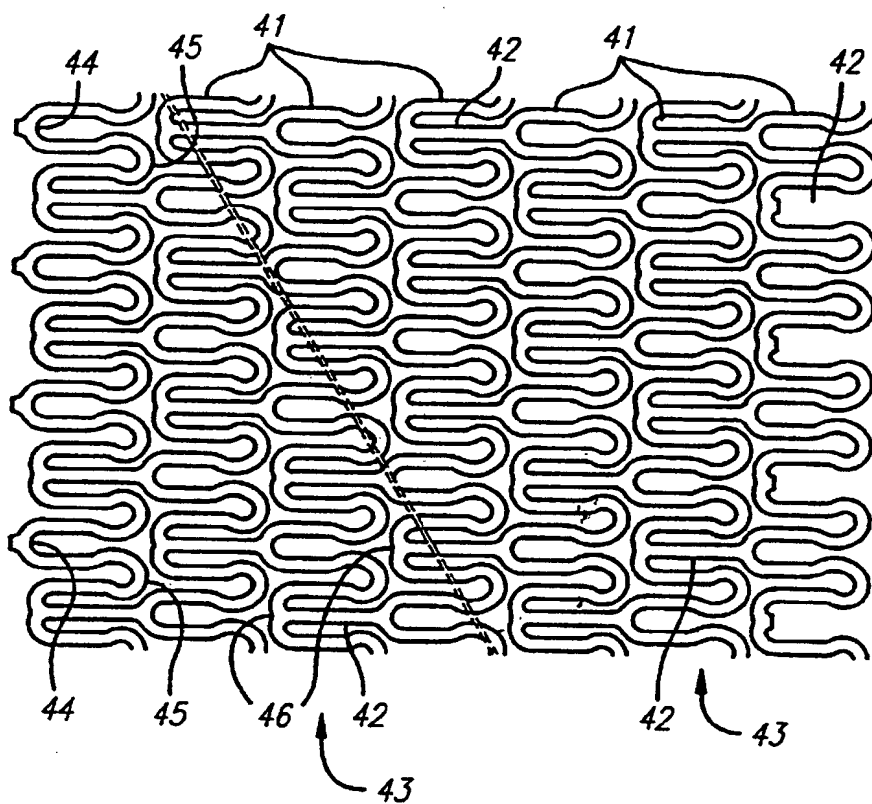
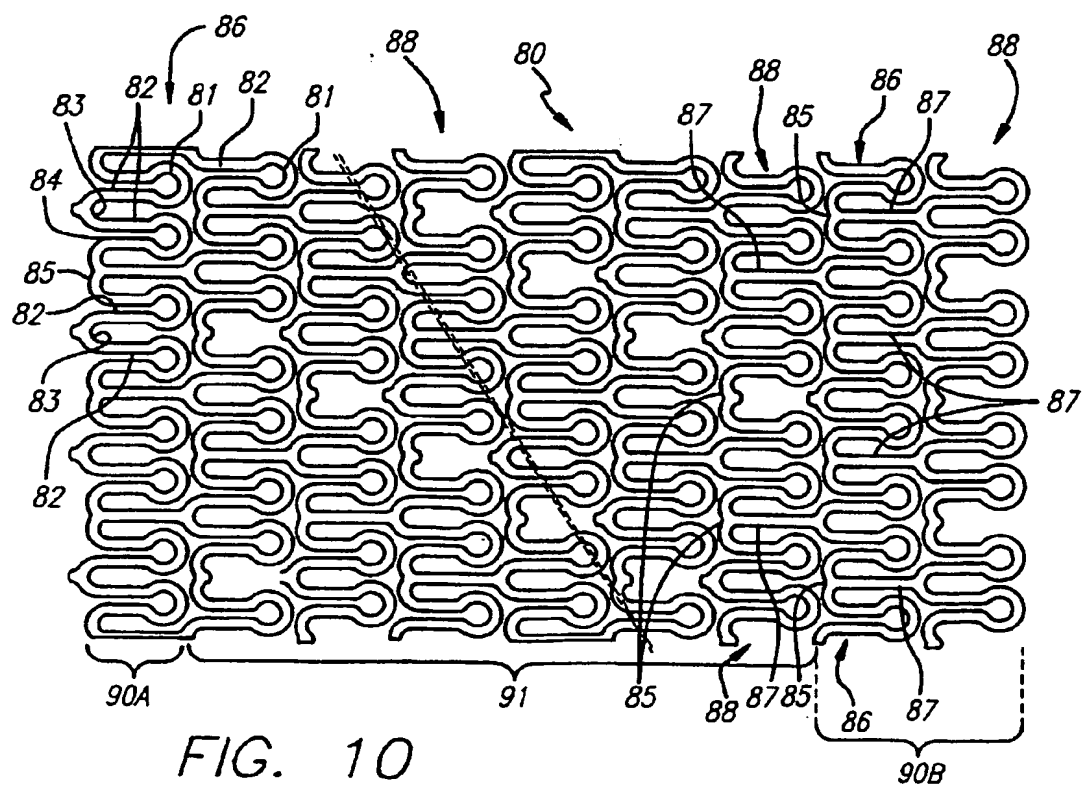
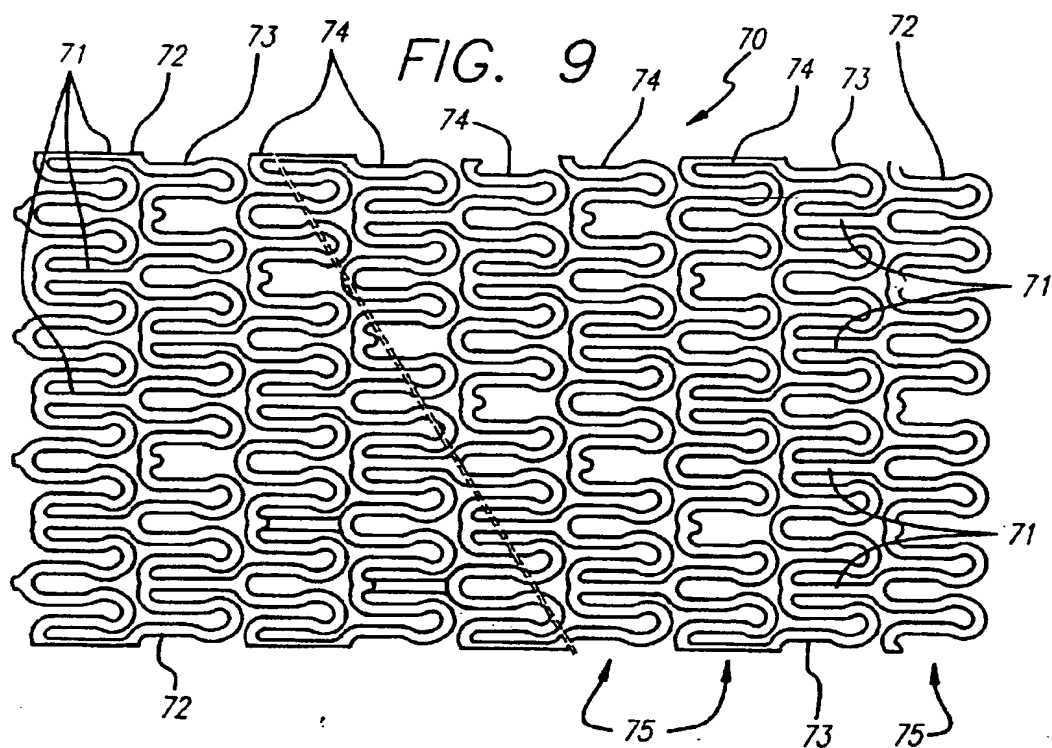
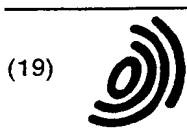


FIG. 8

FIG. 7B







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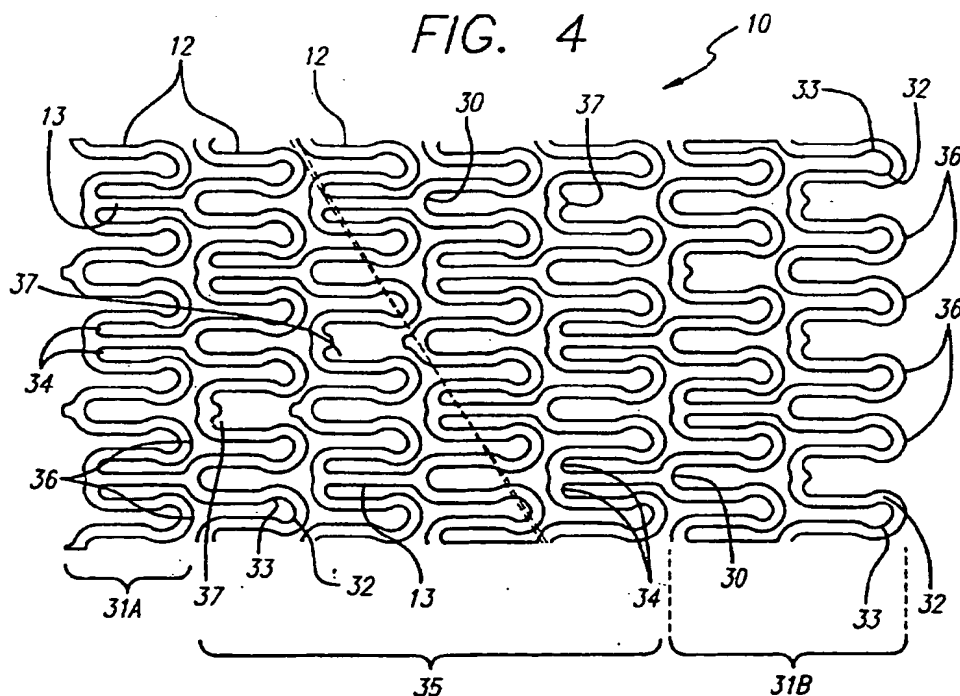
(30) Priority: **16.01.1998 US 8366**

(71) Applicant: **Advanced Cardiovascular Systems,
Inc.**
Santa Clara, CA 95054-8167 (US)

(54) **Flexible stent and method of use**

(57) The invention is directed to an expandable stent for implantation in a body lumen, such as an artery. The stent consists of a plurality of radially expandable

cylindrical elements generally aligned on a common longitudinal stent axis and interconnected by one or more interconnecting members placed so that the stent is flexible in the longitudinal direction.





European Patent
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EUROPEAN SEARCH REPORT

Application Number
EP 99 30 0297

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
P, X	WO 98 22159 A (BEYAR MORDECHAY ; BEYAR RAFAEL (IL); GLOBERMAN OREN (IL); MEDTRONIC) 28 May 1998 (1998-05-28) * figures 2,3 * * figures 12-16 * * page 3, line 7 - line 25 * * page 4, line 10 - line 27 * * page 5, line 1 - line 9 *	13, 15, 16, 18-20	A61F2/06
Y	---	17	
A	---	14, 21-24	
Y	WO 97 25937 A (JANG G DAVID) 24 July 1997 (1997-07-24) * figure ALL * * page 9, line 34 - page 11, line 31 * * page 12, line 9 - page 14, line 14 * * claims 1-10 *	17	
A	---	19	
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A	---	14, 15, 24	
E	DE 299 04 817 U (AMG HANDELSGESELLSCHAFT FUER A) 27 May 1999 (1999-05-27) * figure 3 * * page 5, line 15 - page 6, line 8 * * claims 1-12 *	1, 4, 5, 7, 9-12	
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The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 21 June 2000	Examiner Mary, C
CATEGORY OF CITED DOCUMENTS X particularly relevant if taken alone Y particularly relevant if combined with another document of the same category A technological background O non-written disclosure P intermediate document		T theory or principle underlying the invention E earlier patent document, but published on, or after the filing date D document cited in the application L document cited for other reasons A member of the same patent family, corresponding document	

EPO FORM 1503 03/92 (P04C01)



European Patent
Office

Application Number
EP 99 30 0297

CLAIMS INCURRING FEES

The present European patent application comprised at the time of filing more than ten claims.

- ☐ Only part of the claims have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims and for those claims for which claims fees have been paid, namely claim(s):
- ☐ No claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims.

LACK OF UNITY OF INVENTION

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

see sheet B

- ☒ All further search fees have been paid within the fixed time limit. The present European search report has been drawn up for all claims.
- ☐ As all searchable claims could be searched without effort justifying an additional fee, the Search Division did not invite payment of any additional fee.
- ☐ Only part of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the inventions in respect of which search fees have been paid, namely claims:
- ☐ None of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims, namely claims:



European Patent
Office

EUROPEAN SEARCH REPORT

Application Number
EP 99 30 0297

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
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			TECHNICAL FIELDS SEARCHED (Int.Cl.6)
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 21 June 2000	Examiner Mary, C
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			

EPO FORM 1503 03 82 (PtdC01)



European Patent
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LACK OF UNITY OF INVENTION
SHEET B

Application Number

EP 99 30 0297

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

1. Claims: 13-18,19-24

A flexible expandable stent comprising a plurality of cylindrical elements formed in serpentine wave pattern and a plurality of interconnecting members, these interconnecting members being positioned so that the center section is longitudinally more flexible than the end sections of the device.

2. Claims: 1-12

A flexible expandable stent comprising a plurality of cylindrical elements, n interconnecting members in the end sections and $n-1$ interconnecting members in the center section to increase the flexibility in the center of the device.

**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 99 30 0297

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
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21-06-2000

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For more details about this annex : see Official Journal of the European Patent Office, No. 12/82